Claims

[c1] 1.A device for configuring an inflatable balloon of a balloon catheter assembly, the device comprising:
a body comprising a plurality of inflatable members defining a channel therebetween, the channel sized to accommodate at least a portion of a balloon catheter, each inflatable member having a balloon contacting portion, the inflatable members inflatable from a first size to a second size in which the balloon contacting portions apply an inward force to a balloon of a balloon catheter assembly disposed in the channel.

[c2] 2.The device of claim 1 wherein the inflatable members are disposed about the circumference of a circle.

[c3] 3.The device of claim 1 comprising at least three inflatable members.

[c4] 4.The device of claim 3 wherein the inflatable members are generally tubular and have a circular cross-section.

[c5] 5.The device of claim 3 wherein the inflatable members are generally tubular and have a generally wedge or pie-shaped cross-section.

[c6] 6.The device of claim 3 wherein the body further comprises a rigid tube in which the plurality of inflatable members are constrained, the tube having a first end with a first opening and a second end with a second opening and a passage therethrough.

[c7] 7.The device of claim 6 further comprising first and second end caps, the first end cap disposed at the first end of the tube across the first opening and the second end cap disposed at the second end of the tube across the second opening.

[c8] 8.The device of claim 7 wherein the inflatable members extend from the first and second end caps, the inflatable members in relative alignment with one another, the first and second end caps supporting the inflatable members.

[c9] 9.The device of claim 8 wherein the first end cap has an opening therethrough sized to receive at least a portion of a balloon catheter therethrough.

[c10] 10.The device of claim 1 wherein the plurality of inflatable members includes at

least two inflatable members disposed end-to-end along the length of the channel.

[c11] 11.The device of claim 1 wherein the plurality of inflatable members are disposed in one or more spirals about the channel.

[c12] 12.The device of claim 1 wherein the plurality of inflatable members includes at least two inflatable members which are circumferentially and axially displaced from one another.

[c13] 13.The device of claim 12 wherein the inflatable members which are circumferentially and axially displaced from one another are shorter in length than the balloon.

[c14] 14.In combination, the device of claim 1 with a balloon portion of a balloon catheter assembly disposed in the channel.

[c15] 15.The device of claim 1 wherein each of the inflatable members has an inflation lumen which opens into the inflatable member at a first end of the device and the balloon has an inflation lumen which opens into the balloon at a second end of the device opposite the first end of the device.

[c16] 16.A device for configuring an inflatable balloon of a balloon catheter assembly, the device comprising:
a body comprising an inflatable member having at least one balloon contacting portion,
a catheter support member constructed and arranged relative to the body to support a balloon catheter assembly so that the balloon is in a region adjacent the balloon contacting portion of the inflatable member.

[c17] 17.The device of claim 16 wherein the inflatable member comprises a plurality of balloon contacting portions.

[c18] 18.The device of claim 17 wherein the balloon contacting portions are spaced about the circumference of a circle and the catheter support member is constructed and arranged to support a balloon of a balloon catheter assembly in a region between the balloon contacting portions.

[c19] 19.The device of claim 17 further comprising a rigid tube in which the inflatable

member is constrained, the tube having a first end with a first opening and a second end with a second opening and a passage therethrough.

[c20] 20.The device of claim 19 further comprising at least one constraining member disposed between adjacent balloon contacting portions.

[c21] 21.The device of claim 20 wherein the constraining member is in the form of a slat.

[c22] 22.The device of claim 16 wherein the balloon contacting portion is made of a compliant material and the remainder of the balloon is made of a non-compliant material.

[c23] 23.The device of claim 16 comprising a plurality of said inflatable member, each of which has a balloon contacting portion, the inflatable members disposed about the circumference of a circle, the catheter support member constructed and arranged to support a balloon of a balloon catheter assembly in a region between the balloon contacting portions.

[c24] 24.The device of claim 16 wherein the inflatable member has an inflation lumen which opens into the inflatable member at a first end of the device and the balloon has an inflation lumen which opens into the balloon at a second end of the device opposite the first end of the device.

[c25] 25.A method of configuring at least a portion of a medical balloon comprising the steps of:providing a device as in claim 1 ;
disposing a medical balloon between the inflatable members;
at least partially inflating the medical balloon;
inflating the inflatable members so that the balloon contacting portions deform portions of the medical balloon inward;
at least partially deflating the medical balloon, the inwardly deformed portions of the medical balloon forming a plurality of balloon folds; and
removing the inflatable members from about the medical balloon.

[c26] 26.The method of claim 25 wherein each of the balloon folds extends along the entire length of the balloon.

[c27] 27.The method of claim 25 wherein each of the balloon folds extends spirally about the balloon.

[c28] 28.A method of configuring at least a portion of a medical balloon comprising the steps of:
providing a device as in claim 8 ;
disposing a medical balloon between the inflatable members;
at least partially inflating the medical balloon;
inflating the inflatable members so that the balloon contacting portions deform portions of the medical balloon inward;
at least partially deflating the medical balloon, the inwardly deformed portions of the medical balloon forming a plurality of balloon folds; and
removing the inflatable members from about the medical balloon.

[c29] 29.The method of claim 28 wherein each of the balloon folds extends along the entire length of the balloon.

[c30] 30.The method of claim 29 wherein each of the balloon folds extends spirally about the balloon.

[c31] 31.A method of configuring at least a portion of a medical balloon comprising the steps of:
providing a device as in claim 15 ;
disposing a medical balloon between the inflatable members;
at least partially inflating the medical balloon;
inflating the inflatable members so that the balloon contacting portions progressively deform portions of the medical balloon inward starting from the first end of the device;
at least partially deflating the medical balloon, the inwardly deformed portions of the medical balloon forming a plurality of balloon folds; and
removing the inflatable members from about the medical balloon.

[c32] 32.The method of claim 31 wherein each of the balloon folds extends along the entire length of the balloon.

[c33] 33.The method of claim 31 wherein each of the balloon folds extends spirally about the balloon.

[c34] 34.A method of configuring at least a portion of a medical balloon comprising the steps of:

a) providing a catheter comprising a medical balloon;

b) disposing a plurality of inflatable members about the medical balloon, each inflatable member having a balloon contacting portion;

c) at least partially inflating the balloon by supplying an inflation fluid thereto;

d) at least partially inflating the inflatable members so that the balloon contacting portions contact the medical balloon and apply an inward force to the medical balloon.

[c35] 35.The method of claim 34 further comprising the steps of:

e) removing at least some of the inflation fluid from the medical balloon; and

f) removing the inflatable members from about the medical balloon.

[c36] 36.The method of claim 34 wherein said inflation fluid is heated.

[c37] 37.The method of claim 34 wherein said inflatable member has a T_g and said inflation fluid is heated to a temperature below the T_g of said inflation fluid.

[c38] 38.The method of claim 35 wherein the inflatable members are symmetrically disposed about the medical balloon and upon inflation apply a sufficient radially inward force to the medical balloon to form a plurality of indentations in the medical balloon, the medical balloon upon removal of the inflation fluid therefrom having a plurality of folds.

[c39] 39.The method of claim 35 wherein the inflatable members are configured to apply a radially inward force to the medical balloon when they are inflated, the medical balloon upon removal of the inflation fluid therefrom having a plurality of folds.

[c40] 40.The method of claim 39 wherein each of the balloon folds extends along the entire length of the balloon.

[c41] 41.The method of claim 39 wherein each of the balloon folds extends spirally about the balloon.

[c42] 42.The method of claim 35 wherein each of the inflatable members has an inflation lumen which opens into the inflatable member at a first end of the inflatable member and

the balloon has an inflation lumen which opens into the balloon at an end of the balloon opposite the first end of the inflatable member.

[c43] 43.The method of claim 42 wherein the inward force is applied progressively along the length of the medical balloon.

[c44] 44.The method of claim 42 wherein the inward force is applied spirally about the medical balloon.

[c45] 45. The method of claim 35 wherein the inflatable members are inflated simultaneously.

[c46] 46.The method of claim 35 wherein the inflatable members are inflated in a predetermined sequence.

[c47] 47.The method of claim 35 wherein the plurality of inflatable members includes a first inflatable member located at a first end of the balloon, a second inflatable member located at the middle of the balloon and a third inflatable member located at a third end of the balloon, the first, second and third inflatable members axially displaced from one another along the length of the balloon.

[c48] 48.The method of claim 47 wherein during step e) the second inflatable member is inflated prior to the first and third inflatable members.

[c49] 49.The method of claim 47 wherein during step e) the first inflatable member is inflated prior to the second inflatable member which is inflated prior to the third inflatable member.

[c50] ~ 50.A method of configuring at least a portion of a medical balloon comprising the steps of:
a) providing a catheter comprising a medical balloon;
b) at least partially inflating the medical balloon with an inflation fluid;
c) applying a plurality of discrete axially spaced inward forces to the medical balloon; and
d) deflating the medical balloon.

[c51] 51.The method of claim 50 wherein the plurality of discrete forces are applied by a plurality of axially spaced inflatable members.

[c52] 52.The method of claim 51 wherein the plurality of discrete forces are simultaneously applied with one another.

[c53] 53.The method of claim 51 wherein not all of the plurality of discrete forces are applied simultaneously.

[c54] 54.The method of claim 50 wherein said inflation fluid is heated.

[c55] 55.The method of claim 54 wherein said inflatable members have a T_g and said inflation fluid is heated to a temperature below the T_g of said inflatable members.

[c56] 56.A medical balloon comprising a pleat, at least a portion of which extends in a direction which is non-parallel to the longitudinal axis of the balloon.

[c57] 57.The medical balloon of claim 56 wherein the pleat has a first end and a second end which is circumferentially and longitudinally displaced from the first end of the pleat.

[c58] 58.The medical balloon of claim 57 wherein the pleat spirals at least partially about a longitudinal axis of the balloon.

[c59] 59.The medical balloon of claim 57 comprising a plurality of pleats each of which has a first end and a second end which is circumferentially and longitudinally displaced from the first end.

[c60] 60.The medical balloon of claim 57 having a body portion comprising a plurality of longitudinally discontinuous pleats.

[c61] 61.A medical balloon having a body portion with a first region with pleating and a second region with pleating, the second region axially displaced from the first region, the pleating in the second region differing in appearance from the pleating in the first region.

[c62] 62.The medical balloon of claim 61 wherein the pleating in the second region is discontinuous from the pleating in the first region.

[c63] 63.The medical balloon of claim 61 wherein the number of pleats in the first region differs from the number of pleats in the second region.